**SUPPLEMENTARY INFORMATION:** The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Merck & Co., West Point, PA 19486, has filed an application requesting approval for the export of the human drug Preservative-Free Intravenous Sodium Edecrin® (ethacrynate sodium) 50 mg ethacrynic acid equivalent/50 mL in 60 mL glass bottle to Germany through the Netherlands for packaging and labeling. This product is used in the treatment of accumulation of fluid in tissues (edema, ascites) due to heart, hepatic, or renal disease as well as edemas of the following origin: Edema or ascites caused by tumor compression, lymphedema, and idiopathic edema. The product is being manufactured by a revised process. The firm has new drug application approval for a product containing a thimerosal preservative. The application was received and filed in the Center for Drug Evaluation and Research on May 17, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by July 24, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: June 26, 1995.

**Betty L. Jones,**

*Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.*

[FR Doc. 95–17236 Filed 7–12–95; 8:45 am]

**BILLING CODE 4160–01–F**

## National Institutes of Health

### Warren Grant Magnuson Clinical Center: Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Scientific and Commercial Development of High Resolution PET Scanner Using Scintillation Cameras

**AGENCY:** National Institutes of Health, PHS, DHHS.

**ACTION:** Notice.

**SUMMARY:** The Nuclear Medicine Department in the Clinical Center at the Warren Grant Magnuson Clinical Center is seeking a collaborator with expertise in imaging equipment. The primary focus of this collaboration will be the development and commercialization of an imaging device that is capable of three distinct types of imaging at high resolution: Single photon planar imaging, single photon emission computed tomography (SPECT), and positron emission tomography (PET). An invention that has set the groundwork for this technology is claimed in U.S. Patent Applications 08/235,310, entitled ''Variable Axial Aperture Positron Emission Tomography Scanner'' (filed April 29, 1994) and (CIP) 08/357,574 (filed December 15, 1994). These patents have been filed for the initial phase of foreign filing (PCT) designating all states. NCI seeks a collaborator that will apply the technology to develop imagers for human subjects and/or for high resolution PET imaging of small animals.

Sponsors will be selected based on their ability to develop and commercialize the new imaging technology. NCI will enter into CRADA negotiations with the chosen sponsor with the intention of awarding a CRADA.

The term of the CRADA(s) is anticipated to be three (3) to five (5) years.

**ADDRESSES:** Inquiries and proposals regarding this opportunity should be addressed to either Michelle Rhyu or Bill Cotreau (Tel # 301–496–0477, Fax# 301–402–2117), Office of Technology Development, National Cancer Institute, Building 31, Room 4A49, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

**DATES:** Interested parties should notify this office in writing by September 11, 1995. Respondents will then be given an additional sixty (60) days for filing a formal proposal.

**SUPPLEMENTARY INFORMATION:** A Cooperative Research and Development Agreement (CRADA) is the anticipated joint agreement to be entered into by NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of October 10, 1987. Under the present proposal, the CRADA will focus on developing the following technology:

An instrument has been devised that utilizes conventional scintillation cameras to support single photon planar imaging, single photon emission computed tomography (SPECT), and positron emission tomography (PET). These multiple capabilities rely on the device's ability to efficiently detect gamma rays at single photon energies (<200 keV) and higher positron annihilation energies (511keV) required for PET. This dual ability is conferred by pivoting the detectors in conventional scintillation devices, which are capable of only SPECT and planar imaging, thereby increasing the path length of the high energy positron in the detector and enabling its detection. The cameras may rotate about a fixed target, or stationary cameras may surround a rotating target. The invention makes PET scanning on small animals feasible, allowing the economical collection of test data. Moreover, the invention presents a promising approach to economically increasing the detection capability of conventional SPECT scanners for humans.

Two broad advantages are provided by the present invention: (1) Resolution of PET is improved from 6mm to 2–3mm, making possible the resolution of organs in small animals. This expands the usefulness of small animals in research, for example in determining how test tracer molecules are incorporated into tumors, or how specific therapies affect tumor growth. The invention affords the advantage of using small animals, which are easier and less costly to maintain than larger animals. The ability to carry out PET analysis on smaller animals also circumvents the need to dissect the animal in order to assay an effect, greatly reducing the number of animals required for a study. (2) Applying this technology to human imagers, the invention provides a cost-effective way of improving diagnostic capabilities for